REMARKS

Initially, Applicants thank the Office for the courtesy extended in the telephone call of 2 December 2009. During that conversation, the Office requested clarification regarding the characterization of Chebiyyam (WO '638)'s Examples 39 and 40 relative to the instantly claimed Form. Applicants believe the comments below address the Office's concerns regarding Chebiyyam (WO '638)'s Examples 39 and 40.

Claims 34, 58 and 63-67 were pending. Claims 58, 63, and 64 are currently cancelled without disclaimer. Claims 1-33, 35-37 and 59-62 were previously cancelled. Applicants respectfully request favorable reconsideration for the reasons below.

35 U.S.C. §112 Rejections

Claim 65 is rejected under 35 U.S.C. §112, second paragraph, for lack of enablement. Applicants believe the amendment to the claim addresses the Office's concerns. Support for the amendment may be found, inter alia, on page 9 of the application as filed. Applicants believe that claim 65 is now in condition for allowance.

35 U.S.C. §102 Rejections

Initially, Applicants would like to thank the Office for its removal of the previous 35 U.S.C. §102 rejections based on Lohray et al. (WO 97/41097; "Lohray (WO '097)"), page 89, Example 41. In the previous response, Applicants noted that the invention of claims 34 and 65-67 was distinguished from Lohray (WO '097)'s Example 41 in the application as filed. The application as filed made it clear that the invention of claims 34 and 65-67 had a different DSC profile, different XRD profile and a different IR than the compound disclosed by Lohray's Example 41.

In the new Office action, claim 34, 66 and 67 stand rejected under 35 U.S.C. §102 as being inherently anticipated by Examples 39 and 40 of Chebiyyam (WO '638). Applicants respectfully note that instant claims are patentable over Chebiyyam (WO '638) for the same reasons they were patentable over Lohray (WO '097). Paragraph [0016] of the current application is provided below for the Office's convenience:

[0016] The present invention also relates to a process for the preparation of 5-[4-[[3-Methyl-4-oxo-3,4-dihydroquinazolin-2-yl]methoxy]benzyl]thiazolidine-2,4-dione potassium salt described in example 41 of our international application number PCT/US97/11522 which is being designated as Form I. Form I of 5-[4-[[3-Methyl-4-oxo-3,4-dihydroquinazolin-2-yl]methoxy]benzyl]thiazolidine-2,4-dione potassium salt has also been prepared from methanol/xylene, methanol, ethanol, isopropanol, ethyl acetate, acetone, dimethyl formamide, 1,4-dioxane, 1,4-dioxane/xylene, diethyl ketone, methylisobutylketone and DMSO and is identical and also matches with the data reported for 5-[4-[[3-Methyl-4-oxo-3,4-dihydroquinazolin-2-yl]methoxy]benzyl]thiazolidine-2,4-dione potassium salt described in our above mentioned international application.

Paragraph [0016] discloses that Lohray (WO '097)'s Example 41 is designated as Form I. Paragraph [0016] also discloses that Form I can be prepared using a **methanol/xylene** system. Paragraph [0016] also discloses that Form I prepared using a methanol/xylene system **is identical with and matches the data reported for the Form I data from Lohray (WO '097)'s Example 41**.

Applicants respectfully note that Chebiyyam (WO '638)'s Examples 39 and 40 use the **methanol/xylene** system described in paragraph [0016] and note that, as disclosed in the application as filed, the potassium salt in Chebiyyam (WO '638)'s Examples 39 and 40 is identical to Lohray (WO '097)'s Example 41. Chebiyyam (WO '638)'s Examples 39 and 40 are provided below for the Office's convenience:

Example-39

Preparation of 5-[4-[[3-methyl-4-oxo-3,4-dihydroquinazolin-2-yl]methoxy] benzyl]thiazolidine-2,4-dione potassium salt

5-[4-[[3-Methyl-4-oxo-3,4-dihydroquinazolin-2-yl]methoxy]benzyl]thiazolidine-2,4dione obtained by following a procedure described in any of Examples 29-38 (100 g, 0.25 M) was dissolved in 1 L of xylene : MeOH (1 : 1) mixture at 80-90 °C, treated with decolourising carbon (20 g) and filtered. To the filtrate was added potassium hydroxide solution (15.6 g of potassium hydroxide dissolved in 200 ml of methanol) slowly over a period of 5-10 min. at 60-70 °C. Stirring was continued at ambient temperature for a period of 1 h. The solid obtained was filtered, washed with methanol (300 ml) and dried at 120 °C for 1 h to yield 5-[4-[[3-methyl-4-oxo-3,4-dihydroquinazolin-2-yl]methoxy]benzyl]thiazolidine-2,4-dione potassium salt as an off- white solid (98 g, Y=89%, P=99.5%).

Example-40

Alternative preparation of 5-[4-[[3-methyl-4-oxo-3,4-dihydroquinazolin-2-yl] methoxy]benzyl]thiazolidine-2,4-dione potassium salt

5-[4-[[3-Methyl-4-oxo-3,4-dihydroquinazolin-2-yl]methoxy]benzyl]thiazolidine-2,4-dione obtained by following a procedure described in any of Examples 29-38 (100 g, 0.25 M) was dissolved in 1 L of xylene : MeOH (1 : 1) mixture at 80-90 °C, treated with decolourising carbon (20 g) and filtered. To the filtrate was added potassium t-butoxide solution (31.56 g of potassium t-butoxide dissolved in 200 ml of methanol) slowly over a period of 5-10 min. at 60-70 °C. Stirring was continued at ambient temperature for a period of 1 h. The solid obtained was filtered, washed with methanol (300 ml) and dried at 120 °C for 1 h to yield

5-[4-[[3-methyl-4-oxo-3,4-dihydroquinazolin-2-yl]methoxy]benzyl]thiazolidine-2,4-dione potassium salt as a white solid (100 g, Y=91%, P=99.6%).

As seen above, Chebiyyam (WO '638)'s Examples 39 and 40 are the methanol/xylene system.

Further, Chebiyyam (WO '638) discloses that it is directed to improved processes of preparing the salts of Lohray (WO '097), e.g., the potassium salt (see for example, page 1, paragraphs 1 and 2). Characterizing data regarding Chebiyyam (WO '638)'s Examples 39 and 40 was not provided in the Chebiyyam application because the compound was previously characterized in the referenced Lohray application.

In short, the potassium salt described in Example 39 and 40 of Chebiyyam is identical to, and has all the same properties as, the potassium salt described in Example 41 of Lohray (WO '097) over which the instant claims have already been determined patentable. Applicants apologize for any previous lack of clarity regarding the relationship between Chebiyyam and Lohray and respectfully request reconsideration.

35 U.S.C. §103 Rejections

Claims 58, 63, and 64 were rejected under 35 U.S.C. §103 as being unpatentable over Chebiyyam (WO '638). These claims are cancelled without disclaimer in the interest of expediting allowance of the claims directed to the novel Form and its process of preparation.

Other Matters

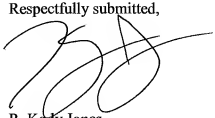
Applicants also wish to note that claims previously presented and directed to Form-I (e.g., claim 35), and arguments thereto, were made in error without deceptive intent. As discussed above, Form-I was disclosed in Lohray (WO '097) and Chebiyyam (WO '638). Applicants apologize for this inadvertent error and any resulting lack of clarity.

Conclusion

Applicants respectfully note that because Applicants have addressed certain comments of the Office does not mean that Applicants concede other comments of the Office. Further, the fact that Applicants have made arguments for the patentability of some claims does not mean there are not other good reasons for the patentability of those or other claims. Applicants also believe that by this amendment, the case is placed in condition for allowance and such action is

respectfully requested. If, however, any issues remain unresolved, Applicants' representative would welcome the opportunity for a telephone interview to expedite allowance and issue.

Respectfully submitted,



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